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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,656	12/21/2001	Aliassghar N. Tofighi	112430.121US1	5535

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EXAMINER
RAMANA, ANURADHA

ART UNIT	PAPER NUMBER
3732	

DATE MAILED: 05/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/027,656	TOFIGHI ET AL.
	Examiner	Art Unit
	Anu Ramana	3732

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 December 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (US 6,117,456).

Regarding claims 1-8, 10, 12, 13, 16-19, 21, 23 and 24, Lee et al. disclose a material for in vivo applications that can be formed or "machined" into an implant including an amorphous calcium phosphate ("first calcium phosphate"), a promoter or "second calcium phosphate" such as calcium metaphosphate, dicalcium phosphate dihydrate etc. as a precursor wherein the calcium to phosphate ratio is in a range of 1.1-1.9 (col. 1, lines 24-26, col. 4, lines 15-18 and lines 40-46, col. 7, lines 50-58, col. 8, lines 1-4 and lines 17-20, col. 12, lines 62-67, col. 13, lines 1-2 and lines 7-13 and col. 14, lines 57-66). It is the Examiner's position that the atomic ratio of calcium to phosphorus of the first calcium phosphate or the second calcium phosphate is an inherent property of the type of calcium phosphate selected as the first calcium phosphate or the second calcium phosphate, respectively. Lee et al. also disclose that the first calcium phosphate is amorphous and the second calcium phosphate may be amorphous or crystalline (i.e., different or greater crystallinity) (col. 11, lines 4-8 and col. 13, lines 17-19).

Although Lee et al. disclose a calcium to phosphate ratio between 1.2 and 1.68, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide an atomic ratio of calcium to phosphorus between 1.2 and 1.68, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller, 105 USPQ 233.*

Further, Lee et al. disclose that a supplementary material may be added to the precursors to improve the hardness or compressive strength of the poorly crystalline hydroxyapatite (col. 22, lines 31-38 and col. 30, lines 54-57). Although Lee et al. do not disclose specific

compressive strengths of 60 MPa or 120 MPa, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have adjusted the hardness or compressive strength of the poorly crystalline hydroxyapatite, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller, 105 USPQ 233.*

Regarding claims 9, 11, 20 and 22, Lee et al. disclose the addition of supplementary material such as biocompatible polymers in particulate (powder) or fiber form in the preparation of resorbable implants (col. 22, lines 63-67 and col. 23, lines 1-15 and lines 22-28).

Regarding claim 14, Lee et al. disclose that the poorly crystalline hydroxyapatite is porous and that the specific grain size of the promoter or second calcium phosphate can be used to control the porosity of the implant. Although Lee et al. do not disclose a specific porosity range, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide a porosity in a range of about 5% to about 30%, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller, 105 USPQ 233.*

Regarding claim 15, Lee et al. disclose sieving precursor materials to a particle size less than 125 microns (col. 29, Table 3).

Regarding claims 25, 28, 31 and 32, the method steps of (a) providing a bone implant as claimed, and (b) securing the bone at a site requiring implantation, whereby the precursor undergoes conversion to poorly-crystalline hydroxyapatite at the implantation site would be performed during normal use of the Lee et al. bone implant for bone implantation (see discussion for claims 1-8 and col. 9, lines 37-48).

Although, Lee et al. do not specifically disclose using the implant material for spinal fusion, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized the poorly crystalline hydroxyapatite for spinal fusion, since it has been held that rearranging parts of an invention involves only routine skill in the art. *In re Japikse, 86 USPQ 7.*

Regarding claims 27 and 30, the method steps would be normally performed when the implant is placed in a human body due to curing of the Lee et al. precursor at a significantly accelerated rate at 37 °C (col. 5, lines 20-28 and col. 8, lines 39-55).

Regarding claims 26 and 29, the method steps would be normally performed depending on the kinetics or duration of the conversion or hardening process of the precursors to poorly crystalline hydroxyapatite (col. 6, lines 6-30). Although Lee et al. do not disclose a duration between 2 weeks and about 6 weeks, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have selected the precursor materials so that the duration of the conversion process is between 2 weeks and 6 weeks, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller, 105 USPQ 233.*

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8, 11, 12, 13, 14-19, 22-32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4, 5, 7, 8 and 14 of U.S. Patent No. 6,287,341. Although the conflicting claims are not identical, they are not patentably distinct from each other because Applicant's invention 1-8 and 13-32 can be obtained from the cited patent claims in view of the following discussion.

Claims Regarding claims 1 and 13, Lee et al. disclose a bone implant made of a reactive amorphous calcium phosphate "precursor" capable of forming poorly crystalline hydroxyapatite in vivo, wherein the precursor has a calcium to phosphate ratio of between 1.2 and 1.68 (col. 3, lines 13-29, col. 8, lines 55-65, col. 11, lines 60-64 and col. 12, lines 65-67).

Although Lee et al. disclose a calcium to phosphate ratio of 1.2 and 1.68, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide an atomic ratio of calcium to phosphorus between 1.2 and 1.68, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller, 105 USPQ 233.*

Lee et al. further disclose that the implant is formulated to improve strength for load bearing applications (col. 13, lines 49-50). It would have been an obvious design choice to one having ordinary skill in the art at the time the invention was made to have made the implant with a compressive strength of 60 MPa or 120 MPa, based on the load bearing application in which the implant is utilized since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller, 105 USPQ 233.*

Regarding claim 2, Lee et al. disclose that the implant can be shaped into the desired form using drills or other such shaping or "machining" tools known in the art (col. 14, lines 51-54).

Regarding claims 3-8 and 16-19, Lee et al. disclose a first calcium phosphate that is amorphous and a second calcium phosphate that may be of any crystalline structure either amorphous, poorly crystalline or with higher crystallinity than the first calcium phosphate wherein the second calcium phosphate is dicalcium phosphate dihydrate, calcium metaphosphate etc., each calcium phosphate having a different calcium to phosphorus ratio (col. 12, lines 20-38, lines 41-43 and lines 46-55).

Regarding claims 11, 12, 14, 22 and 23, Lee et al. disclose that the resorbability of an implant can be modified by altering its porosity wherein bioerodible polymers in the form of whiskers or fibers can be utilized to provide a desired level of porosity (col. 13, lines 22-34 and col. 23, lines 12-13).

Although Lee et al. do not disclose a porosity between 5% and 30%, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided a porosity between 5% and 30%, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller, 105 USPQ 233.*

Regarding claim 15, Lee et al. disclose implant material having a particle size less than 100 microns (col. 20, lines 30-39).

Regarding claims 25 and 31, the method steps of (a) providing a bone implant with the specifics as claimed, and (b) securing the bone at a site requiring implantation, whereby the precursor undergoes conversion to poorly-crystalline hydroxyapatite at the implantation site would be performed during normal use of the Lee et al. bone implant either for bone implantation or for spinal fusion (see discussion for claim 1, col. 15, lines 30-34 and col. 16, lines 13-40).

Regarding claims 28 and 32, the method steps of (a) providing a bone implant with the specifics as claimed, and (b) securing the bone implant at a site requiring implantation, whereby the first and second calcium phosphates undergo conversion to poorly crystalline hydroxyapatite at the implantation site be performed during normal use of the Lee et al. bone implant either for bone implantation or for spinal fusion (see discussion for claims 3-8, col. 15, lines 30-34 and col. 16, lines 13-40).

Regarding claims 27 and 30, the method steps would be normally performed when the implant is placed in a human body due to curing of the Lee et al. precursor at a significantly accelerated rate at 37 °C (col. 10, lines 41-44 and col. 15, lines 30-34).

Regarding claims 26 and 29, the method steps would be normally performed depending on the kinetics or duration of the conversion or hardening process of the precursors to poorly crystalline hydroxyapatite (col. 5, lines 17-41). Although Lee et al. do not disclose a duration between 2 weeks and about 6 weeks, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have selected the precursor materials so that the duration of the conversion process is between 2 weeks and 6 weeks, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller, 105 USPQ 233.*

Claims 9, 10, 20 and 21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4, 5, 7, 8 and 14 of U.S. Patent No. 6,287,341 in view of Lee et al. (US 6,117,456). Although the conflicting claims are not

identical, they are not patentably distinct from each other because Applicant's invention 9-10 and 20-21 from the cited patent claims in view of the following discussion.

U.S. Patent No. 6,287,341 discloses that the resorbability of an implant can be modified by altering its porosity wherein bioerodible polymers in the form of whiskers or fibers can be utilized to provide a desired level of porosity (col. 13, lines 22-34 and col. 23, lines 12-13).

Lee et al. teach addition of supplementary materials such as biocompatible or bioerodible polymers in particulate or fiber form (col. 22, lines 42-44 and lines 63-67; and col. 23, lines 22-28).

It would have been obvious to one of ordinary skill in the art to substitute polymer fiber for polymer powder as taught by Lee et al. wherein so doing would amount to mere substitution of one functionally equivalent material for another within the same art and the selection of any of these materials would work equally well in the claimed implant for the intended purpose.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicant's attention is directed to Agrawal et al. (US 6,187,329): col. 1, lines 44-52.

Applicant's attention is directed to Lee et al. (US 6,132,463): Figure 9 and col. 3, lines 57-67 and col. 4, lines 1-9.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (703) 306-4035. The examiner can normally be reached Monday through Friday between 8:30 am and 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Shaver can be reached at (703) 308-2582. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-2708 for regular communications and (703) 308-2708 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

AR Anuradha Ramana
April 25, 2003

EDUARDO C. ROBERT
PRIMARY EXAMINER